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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/693,442
Filing Date: December 29, 2000
Appellant(s): FLEISCHNER, ALBERT

Mark Pohl
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10 August 2006 appealing from the Office action mailed 20 June 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: Appellant indicates that claims 1-7, 17-26, and 28-40 stand rejected under USC 103 (see top of page 4, item F-iii, and page 10 - Item III, of the brief). However, only claims 1, 2, 35, and 36 stand rejected under in the first USC 103 rejection of record, and only claims 1, 2, 7-9, 35, and 36 stand rejected in the second USC 103 rejection of record. Claims 3-6, 17-26, 28-34, and 37-40 do not stand rejected under USC 103 (thus, as discussed in the Examiner-Initiated Interview Summary dated 16 October 2006, claims 3-6, 17-26, 28-34, and 37-40 are or would be allowable, if amended accordingly - since the USC 112, first paragraph rejections of record have been withdrawn based upon Appellants arguments presented within the brief, as set forth below under **Grounds for Rejection**).

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Tulp et al. Effect of Hoodia plant on Weight Loss in Congenic Obese LA/Ntul//-cp Rats. FASEB Journal. March 20, 2002. Vol. 16, No. 4, page A648, Meeting Abstract - BIOSIS abstract.

Barnett, A. In Africa the Hoodia Cactus Keeps Men Alive. Now Its Secret is 'Stolen' to Make Us Thin. The Observer. June 2001, 4 pages - as provided by the Internet Website http://blackherbals.com/hoodia cactus.htm.

Habeck, M. A Succulent Cure to End Obesity. Drug Discovery Today. March 2002. Vol. 7, No. 5, pages 280-281.

Kahn, T. Prickly Dispute Finally Laid to Rest: San Reach Agreement with CSIR Over Use of Appetite-Suppressing Cactus. Business Day (Johannesburg). March 2002, 4 pages - as provided by the Internet website www.grain.org.

6,376,657 Van Heerden et al. 04-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The two USC 112, first paragraph rejections of record are withdrawn based upon Appellant's arguments presented within the Appeal Brief filed 10 August 2006.

Claim Rejections - 35 USC § 103

Claims 1, 2, 35, and 36 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Tulp et al. (FASEB Journal, March 2001 - BIOSIS Meeting Abstract) or over Barnett (The Observer, June 2001 - as provided by the internet article entitled "In Africa the Hoodia cactus keeps men alive. Now its secret is 'stolen' to make us thin") or over Habeck (Drug Discovery Today article entitled "A succulent cure to end obesity", March 2002) or over Kahn (Business Day - Johannesburg, March 2002 - as provided by the internet article entitled "San reach agreement with CSIR over Hoodia") or over Van Heerden et al. (US 6,376,657), for the reason set forth in the previous Office action which are restated below.

Each of the cited references clearly and beneficially teach that the cactus plant *Hoodia gordonii* (and/or extracts thereof - such as the sap: as disclosed in US '657) is effective as a weight-loss and/or anti-obesity agent for losing weight when orally administered. For example: Tulp et al. beneficially teach that a ground-up slurry of Hoodia gordonii plant effectively decreased the body weight of obese rats and that the results of this study indicate that orally administered *Hoodia gordonii* has strong potential for clinical appetite regulation and weight control (see BIOSIS - Meeting Abstract). Barnett also beneficially teaches that the cactus plant *Hoodia gordonii* (and extracts thereof) is well known to be useful as an anti-obesity agent (see entire 3 page document). Habeck also beneficially teaches that the cactus plant *Hoodia gordonii* (and extracts thereof) is well known to be useful as an anti-obesity agent (see entire 2 page document). Kahn also beneficially teaches that the cactus plant *Hoodia gordonii* (and extracts thereof) is well known to be useful as an anti-obesity agent (see entire 4 page document). Van Heerden et al. also beneficially teach a weight-loss composition which comprises *Hoodia gordonii* sap extract as an active ingredient therein, as well as a method of reducing weight in a subject in need thereof via administering an effective amount of the *Hoodia gordonii* extract (see entire document including, e.g., Abstract, cols 35-36 and 55-70, Figures, claims).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to repeatedly administer a weight-reducing amount of *Hoodia gordonii* to an obese and/or overweight subject, based upon the beneficial teachings of each of the cited references with respect to its well recognized activity in promoting weight loss and/or acting as an anti-obesity agent. The adjustment of particular conventional working conditions - e.g., determining appropriate, suitable time periods and intervals for orally administering such a

Hoodia gordonii weight-loss product - is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, especially given that the skilled dietary artisan would clearly take into account the amount of weight an overweight/obese subject needs to lose and administer such a weight-loss product accordingly - e.g., on a commonly-employed once or more daily basis for an extended period of time (as instantly claimed) so as to achieve a desired amount of weight loss/reduction in the overweight/obese subject.

Thus, the claimed invention as a whole is clearly *prima facie* obvious over each of the cited references, especially in the absence of evidence to the contrary.

Claims 1, 2, 7-9, 35, and 36 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Tulp et al. (FASEB Journal, March 2001 - BIOSIS Meeting Abstract), Barnett (The Observer, June 2001 - as provided by the internet article entitled "In Africa the Hoodia cactus keeps men alive. Now its secret is 'stolen' to make us thin), Habeck (Drug Discovery Today article entitled "A succulent cure to end obesity", March 2002), Kahn (Business Day - Johannesburg, March 2002 - as provided by the internet article entitled "San reach agreement with CSIR over Hoodia"), and Van Heerden et al. (US 6,376,657), in view of Fleischner (US 6,420,350) and the admitted state of the art, for the reason set forth in the previous Office action which are restated below.

The primary references are relied upon for the reasons set forth above. None of the primary references expressly teach administering such a *Hoodia gordonii* weight loss/anti-obesity product in combination with the other claimed ingredients.

Fleischner discloses weight-loss compositions comprising conventional art-recognized ingredients commonly employed therein such as glucosamine, caffeine, green tea extract, ma huang (ephedra/ephedrine), chromium, and/or vanadium (see entire document).

In addition, as readily admitted by Applicant, each of the additional recited ingredients is well known and recognized in the prior art to be effective for reducing weight and/or enhancing weight loss (see, e.g., paragraphs [0026] - [0075] of the instant specification).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the prior art for the same purpose - as well as to use the combined prior art ingredients for such purpose (i.e., for promoting weight loss/reducing weight in a subject) and for the following reasons. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose, as well as to use such a combination for that purpose (within a method of reducing weight). The idea for combining them flows logically from their having been used individually in the prior art. In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients.

Accordingly, a method of reducing weight (as instantly claimed) via consuming a composition comprising one, two, and/or several conventional weight loss ingredients would have been obvious to one of ordinary skill in the art at the time the claimed invention was made having the above cited references as well as the admitted state of the art before him/her. The result-effective adjustment of particular conventional working conditions (e.g. determining appropriate dosage intervals and/or durations of treatment, or using a particular portion of the *Hoodia gordonii* plant) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

(10) Response to Argument

The arguments presented by Appellant against the two USC 103 rejections of record will be addressed by the Examiner in the order in which the references appear in the above USC 103 rejections.

However, at the outset, with regard to Appellant's arguments concerning the limitations of instant claims 3 and 19: that none of the cited references teach the combination of claims 3 and 19 - i.e., that the cited references do not teach the combination of *Hoodia gordonii* and a secondary compound selected from glucosamine and a stimulant, it is reemphasized that claims 3 and 19 were not rejected in either of the USC 103 rejections above (based upon the instantly disclosed synergistic activity provided by the secondary compound and *Hoodia gordonii* with respect to the recited limitation in claims 3 and 19 regarding the secondary stimulant and/or

glucosamine being "in an amount sufficient to lessen the amount of *Hoodia gordonii* required for body weight reduction") - nor were claims that depend therefrom. Accordingly, these arguments have not been addressed below as they do not pertain to the USC 103 rejections of record. For additional information, please see the Examiner-Initiated Interview dated 16 October 2006 concerning allowable independent claims which incorporate such limitations therein.

Regarding the cited reference by Tulp et al, Appellant argues that Tulp et al. teach that laboratory rats with impaired thermogenesis and sugar metabolism can lose weight when given *Hoodia gordonii* (see, e.g., pages 12 of Appeal Brief), that the Tulp et al. teachings fail to render the claim obvious because the results presented therein are not indicative of efficacy in humans (see, e.g., page 23 of Appeal Brief), that this type of mutated obese rat can loose weight if administered *Hoodia gordonii* for a short period of time, but this reference fails to provide any assurance of success in humans because these mutant obese rats are so different from normal rats and from normal human beings and, thus, provides a mere invitation to experiment (see, e.g., page 24 of Appeal Brief).

However, it is clear from the teachings of Tulp et al. that feeding the *Hoodia gordonii* plant (in the form of a homogenate of dehydrated *Hoodia gordonii*) to the congenic obese rat models used therein was a laboratory experiment designed to determine the effectiveness of *Hoodia gordonii* to cause weight reduction in the obese rats (i.e., congenic obese rat models used for studying obesity). The results of this 3-week study clearly demonstrate that *Hoodia gordonii* is useful and effective as a weight loss agent in treating obesity based upon the significant reduction in food intake, body weight, and body fat mass observed in the obese rats fed *Hoodia*

gordonii diets, whereby the body weights of the obese rats decreased to near normal (without observable side effects) during the study. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to repeatedly administer a weight-reducing amount of *Hoodia gordonii* to an obese and/or overweight subject (including a human subject), based upon the beneficial teachings provided by Tulp et al. with respect to its demonstrated ability to significantly reduce food intake, body weight, and body fat mass in the obese rat models used in their study. As discussed above, the adjustment of particular conventional working conditions - e.g., determining appropriate, suitable time periods and intervals for orally administering such a *Hoodia gordonii* weight-loss product - is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, especially given that the skilled dietary artisan would clearly take into account the amount of weight an overweight/obese subject needs to lose and administer such a weight-loss product accordingly - e.g., on a commonly-employed once or more daily basis for an extended period of time (as instantly claimed) so as to achieve a desired amount of weight loss/reduction in the overweight/obese subject.

Regarding the cited articles by Barnett, Habeck, and Kahn: Appellant argues that Barnett teaches that *Hoodia gordonii* causes transient appetite suppression, and that Barnett does not teach weight loss or the claimed administration periods (see, e.g., pages 12 and 19 of the Appeal Brief); that Habeck teaches the compound derived from *Hoodia gordonii* does not cause weight loss, that Habeck fails to teach the administration regime of claim 2, that Habeck is merely an invitation to experiment, and that the compound derived from *Hoodia gordonii* taught therein

might actually promote weight gain in humans (see, e.g., pages 11, 20, and 21 of the Appeal Brief); that Kahn teaches transient appetite suppression, and that Kahn does not teach weight loss (see, e.g., pages 12 and 19 of the Appeal Brief).

With respect to Appellant's arguments over the Barnett, Habeck, and Kahn references (as they pertain to the claims actually rejected under USC 103), the Examiner could find no teaching or suggestion within the Barnett or Kahn references that *Hoodia gordonii* (or extracted compound derived therefrom) causes appetite suppression in a transient manner, as argued (and Appellant did not provide any citations within these two references to support this contention). In addition, the Examiner could find no teachings or suggestions within the Habeck reference that the *Hoodia gordonii* derived compound does not cause weight loss or that it might actually promote weight gain (again, Appellant did not provide any citations within the Habeck reference to support these contentions). To the contrary, it is clear from the teachings of Habeck that preclinical treatment studies with rats, mice, and dogs with the *Hoodia gordonii* derived compound produced a significant weight loss and had a good safety profile therein; and that overweight men in their study who consumed the extracted *Hoodia gordonii* derived compound (twice daily for 15 days) achieved a 30% reduction in calorie intake accompanied by a significant reduction in body fat, that obesity is a chronic relapsing problem and you need a treatment that is going to work safely and effectively over much longer periods of time, and that the next step will include taking a closer look at the dosing interval (see, e.g., last column on page 280, and page 281 of Habeck). Thus, it is unclear to the Examiner as to how the skilled artisan would construe the Habeck reference as teaching no weight loss and/or promoting weight gain therewith. Please note that the individually cited references by Barnett, Habeck, and Kahn

(as used within the first USC 103 rejection above) are similar teachings each of which reasonably disclose that the cactus plant *Hoodia gordonii* (and extracts thereof) is well known to be useful as an anti-obesity agent (as discussed above). More fully, each of these teachings focus on the commercial use and/or exploitation of indigenous knowledge derived from the San tribesmen (also known as Kung and/or Xhomani bushmen) with respect to the ability of the *Hoodia gordonii* cactus to satiate hunger and quench thirst: i.e., over thousands of years these tribesmen consumed the upper portion (stems) of the *Hoodia gordonii* cactus to stave off hunger and thirst on long hunting trips (so as to resist temptation to eat their kill before returning to camp). These three articles each further discuss the subsequent efforts by the Council for Scientific and Industrial research (CSIR) of South Africa (through the pharmaceutical firms Phytopharm and Pfizer) to then take this cactus and extract an isolated compound therefrom (please note that the isolated compound reads upon an extract - as discussed in the USC 103 rejections, since the isolated compound is, in fact, extracted from *Hoodia gordonii*) which acts as an anti-obesity, slimming agent. Thus, from the teachings of each of these three articles, it would have clearly been obvious to the ordinary artisan that by consuming the cactus plant itself, an anti-obesity, weight-loss effect would have reasonably been expected. For example, the title of each of these articles (Barnett: "In Africa the Hoodia cactus keeps men alive. Now its secret is 'stolen' to keep us thin"; Habeck: "A succulent cure to end obesity"; Kahn: "Prickly Dispute Finally Laid to Rest: San Reach Agreement with CSIR Over Use of Appetite-Suppressing Cactus") would reasonably suggest to the ordinary artisan that consuming the cactus itself would provide an anti-obesity, weight loss effect (based upon the indigenous knowledge provided by the San tribesmen concerning the ability of *Hoodia gordonii* to satiate hunger - as expressly

taught by each of these three articles). In addition, each of these three articles discusses obesity and the effect of the *Hoodia gordonii* extracted compound to effectively act as an anti-obesity, weight loss agent. Further, Barnett expressly discloses the following: "Phytopharm ... said it had discovered a potential cure for obesity derived from an African cactus" - referring to the *Hoodia gordonii* cactus (see, e.g., first page, fourth paragraph); and "As for the San, although they remain annoyed that, in their view, they were almost swindled and they can't help but be amused by the prospect of Westerners using the hoodia plant to slim down" (third page - final sentence). Accordingly, based upon the teachings provided by each of these three references, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to reduce body weight via repeatedly administering (consuming) *Hoodia gordonii* for a result-effective time. With regard to Appellant's argument that the cited references do not expressly teach the claimed administration period (including as recited in claim 2), it is reemphasized (as discussed fully above) that the adjustment of particular conventional working conditions - e.g., determining appropriate, suitable time periods and intervals for orally administering such a *Hoodia gordonii* weight-loss product - is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, especially given that the skilled dietary artisan would clearly take into account the amount of weight an overweight/obese subject needs to lose and administer such a weight-loss product accordingly - e.g., on a commonly-employed once or more daily basis for an extended period of time (as instantly claimed) so as to achieve a desired amount of weight loss/reduction in the overweight/obese subject.

Regarding the cited reference by Van Heerden et al., Appellant repeatedly argues that the teachings of Van Heerden et al. fail to teach weight loss, but instead that the *Hoodia*-derived compounds (including the same *Hoodia*-derived compound discussed by Barnett, Habeck, and Kahn) cause transient appetite suppression followed by appetite stimulation and a net body weight gain and/or that Van Heerden et al. actually teaches that *Hoodia* extracts cause body mass to increase, not decrease and thus actually teaches away from the claimed invention (see, e.g., pages 11, 15, 17, 18, 19, 28, and 29).

However, these arguments are not deemed persuasive as they are not considered complete interpretations of the overall teachings provided by Van Heerden in which Van Heerden clearly disclose that *Hoodia* extract preparations are beneficially useful for treating obesity (i.e., for weight loss). See, e.g., cols 56-64 in which Van Heerden expressly teaches that orally consumed pure sap from the *Hoodia gordonii* plant (which reasonably reads upon *Hoodia gordonii* as claimed since *Hoodia gordonii* sap is, in fact, crude *Hoodia gordonii* plant material) produced statistically significant reductions in body weights when compared to a vehicle-treated control group from 48 hours to the end of the study (including, e.g., when given on a daily basis) - see entire document including, e.g., Abstract, cols 35-36 and 55-70, Figures, claims. In fact, Van Heerden literally teaches "that the expression --- 'appetite suppressant' --- is used herein to denote activity which tends to limit appetite and/or increase the sense of satiety, and thus tends to reduce caloric intake; this in turn tends to counteract obesity. Accordingly, this invention extends to a method of treating, preventing, or combating obesity in a human or non human animal" and that a preferred embodiment of this aspect of the invention includes a *Hoodia gordonii* extract (e.g., a sap extract) containing an active anti-obesity compound therein; as well as a preferred

dosage range of the *Hoodia gordonii* extract (e.g., sap extract) to be given on a daily basis (see, e.g., col 70, lines 14-44). It should again be noted that the teachings of Van Heerden et al. (assignee CSIR) with respect the use of their *Hoodia gordonii* preparations for weight reduction are well documented by others in the prior art (as evidence - see, e.g., the cited references by Barnett, Habeck, and Kahn - to name a few). Accordingly, it would seem that Appellant would have been well aware that the CSIR patented *Hoodia* product was being used for weight reduction at the time of the instantly claimed invention.

With respect to the second 103 rejection above (over the combination of references discussed individually above, in view of US patent No. 6,420,350 by Fleischner), Appellant has argued and discussed the cited references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which make up the state of the art with regard to the claimed invention. Appellant's claimed invention fails to patentably distinguish over the state of the art represented by the references. Appellant further argue that the combination of references do not expressly teach the time periods/intervals instantly claimed. However, as stated above (and previously), the adjustment of particular conventional working conditions - e.g., determining appropriate, suitable time periods and intervals for orally administering such a *Hoodia gordonii* weight-loss product - is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, especially given that the skilled dietary artisan would clearly take into account the amount of weight an overweight/obese subject needs to lose and administer such a weight-loss product accordingly - e.g., on a commonly-employed once or more

daily basis for an extended period of time (as instantly claimed) so as to achieve a desired amount of weight loss/reduction in the overweight/obese subject. Obviously, the more overweight/obese a subject is, the longer he/she would need to take such a weight-loss product in order to achieve the desired amount of weight loss/reduction. Accordingly, this type of adjustment would clearly have been obvious to one of ordinary skill in the art at the time the claimed invention was made. With respect to the claimed limitation of administering the *Hoodia gordonii* a plurality of times, each one of said times occurring before the *Hoodia gordonii* causes an appetite-stimulating effect (as recited in claim 35), this limitation is not deemed to provide patentable distinction to the instantly claimed method since the overall teachings of the cited references clearly show that *Hoodia gordonii* provides an appetite-suppressing effect and, therefore, would not typically be considered to provide an appetite-stimulating effect, especially when routinely consumed for the purpose of reducing weight (regardless, the conventional once or more daily consumption of *Hoodia gordonii* would meet this ambiguous limitation).

As such, the Patent Office has met the burden in showing that the invention defined by claims 1, 2, 35, and 36 is *prima facie* obvious over each of the individual references cited within the first USC 103 above, and has met the burden in showing that the invention defined by claims 1, 2, 7-9, 35, and 36 is *prima facie* obvious over the combination of cited references within the second USC 103 rejection above, for the reasons discussed *supra*.

Appellant further argue secondary indicia of non-obviousness (see, e.g., pages 27-31 of the Appeal Brief) including unexpectedly successful results, achieving a new and different function, and widespread copying by competitors.

With respect to unexpectedly successful results whereby Appellant points to the Declaration filed 21 December 2005 which states that the inventor's results are unexpected because one would expect weight gain not weight loss, and the weight loss data provided therein shows that humans consuming the Trim Spa® (*Hoodia*) diets achieved a measurable reduction in body mass after twelve weeks of use which was significantly superior to placebo in generating such weight loss. However, the data provided in the 21 December 2005 is not unexpected for the reasons fully discussed above - i.e., one of ordinary skill in the art would reasonably expect to observe body weight reduction (not weight gain as argued) in an obese and/or overweight human repeatedly administered a weight-reduction amount of *Hoodia gordonii* a plurality of times, based upon the beneficial teachings provided by the cited references with respect to its well recognized activity in promoting weight loss and/or acting as an anti-obesity agent (as discussed fully above).

With respect to achieving a new and different function - i.e., that the inventor has achieved a function which is not only different but the direct opposite of the prior art - i.e., that the prior art teaches that the *Hoodia*-derived compound functions to increase body mass, not decrease body mass using *Hoodia gordonii* itself. However, for the reasons discussed immediately above, one of ordinary skill in the art would also reasonably expect to observe a decrease in body mass (not an increase in body mass as argued) in an obese and/or overweight human repeatedly administered a weight-reduction amount of *Hoodia gordonii* a plurality of

times, based upon the beneficial teachings of each of the cited references with respect to its well recognized activity in promoting weight loss and/or acting as an anti-obesity agent (as discussed fully above).

With respect to widespread copying, which Appellant argues indicates non-obviousness: firstly, more than a mere fact of copying the invention (instead of using the prior art) is necessary to make that action significant because copying may be attributable to other factors such as a lack of concern for patent property or contempt for the patentees ability to enforce the patent, or when the copy is not identical to the claimed product and the other manufacturer had not expended great effort to develop its own solution (see, e.g., MPEP 716.06, including the cited case law therein); secondly, one would reasonably expect there to be a certain amount of copying of the instantly claimed Trim Spa® product by competitors given that Appellant's commercial Trim Spa® product has been highly publicized.

In addition, there is a nexus requirement between the merits of the claimed invention and the evidence of secondary consideration (see, e.g., MPEP 716.01(b)). In weighing the evidence, the ultimate determination of patentability must be based on consideration of the entire record, by a preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence. Further, although the record may establish evidence of secondary consideration which are indicia of non-obviousness, the record may also establish such a strong case of obviousness that the objective evidence of nonobviousness is not sufficient to outweigh the evidence of obviousness (see, e.g., MPEP 716.01(d) - including the case law cited therein). In considering the entire record, the preponderance of evidence, and Appellant's arguments concerning the secondary indicia of non-obviousness, the Examiner is not persuaded and, thus,

maintains that the USC 103 rejections of record are proper, especially given the USC 103 rejections set forth above establish a strong case of obviousness such that the objective evidence of nonobviousness is not sufficient to outweigh the evidence of obviousness with respect to the invention defined by claims 1, 2, 7-9, 35 and 36.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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October 25, 2006

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